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Evaluation of tibial nerve stiffness by elastography in distinguishing diabetic polyneuropathy and small fibre neuropathy in patients with type 2 diabetes

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Abstract

Background & Objective: We investigated the comparison of shear wave elastography (SWE) method with electromyography (EMG) in diabetic polyneuropathy (DPN) cases in patients with type 2 diabetes mellitus (T2 DM) and evaluated the diagnosis of small fiber neuropathy (SFN) with SWE, which was normal in EMG. *Methods:* Fifty T2 DM patients and 16 healthy controls were included in the study. Patients were divided into 3 groups according to EMG results; i.e., the group respectively with small fiber neuropathy, sensory axonal neuropathy, and sensorimotor neuropathy. Sonographic measurements were made at the poplitial fossa and medial malleolus level in the study groups, and the results were evaluated statistically. *Results:* Fifty T2DM patients and 16 control group patients were included in the study. In the tibial nerve measurements from the popliteal fossa level of the patients, a significant difference was observed in the area under the curve between the control group and the SFN on the right side (p=0.044). In the measurements of the patients from the medial malleolus level, a significant difference was observed in the shear wave velocity on the right side between the control and SFN groups, and also between the SFN group and the sensorimotor neuropathy group (p=0.047).
Conclusion: In this study, significant differences were found between DPN patients and healthy controls when evaluated with cross-sectional area. Thus, SWE may be an alternative objective diagnostic method even in cases where DPN cannot be diagnosed with electrophysiological tests.

Keywords: single fiber neuropathy, ultrasonography, shear wave elastography, diabetes mellitus

INTRODUCTION

Diabetic peripheral neuropathy (DPN) is one of the most common complications observed in patients with type 2 diabetes mellitus (T2DM) and can be seen in approximately 45% of patients.[1] Because DPN causes sensory abnormalities in patients, it can cause clinical conditions that can lead to foot ulcers, gangrene and amputation in patients.[2] Therefore, early detection of patients with DPN is important in order to prevent the development of such complications. Diagnosis of DPN is made by electrophysiological examinations along with symptoms and signs. Electrophysiological examinations are accepted as the gold standard in the diagnosis of DPN since they are objective and reproducible. Nevertheless, the invasiveness, cost and discomfort of the technique limit its applicability.[3] In addition, although the patients have DPN clinically, there are many cases where electrophysiological tests are normal and these are called early-stage DPN.[4]

Shear wave elastography (SWE) is a new noninvasive ultrasound method to quantitatively evaluate the elastic properties of tissues. It is widely used in the examination of breast, liver, and prostate diseases, and there is increasing interest in the use of SWE in the evaluation of neuromuscular pathologies, including DPN.[5,6] SWE has been reported to have high specificity in the diagnosis of DPN, and started to be used in focal nerve entrapments. Neuropathy could be evaluated with certain morphological changes such as increased cross-sectional area (CSA) and decreased echoes in T2DM.[7,8] Diagnostic value of SWE was investigated in patients with T2 DM and it has been found that the DPN group showed significantly higher tibial nerve stiffness compared with healthy patients and T2 DM patients without DPN.[9,10] They predicted

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that subclinical DPN diagnosis can be made with SWE.[10] In the pathophysiology of nerve stiffness; high amounts of sorbitol and fructose accumulation in nerve cells cause an increase in intracellular osmotic pressure, and in the other mechanism, when microvascular dysfunction occurs in the nerves, the ion balance is disrupted and Ca2+ increases in the cells, causing neuronal damage and ultimately edema in the nerve cells.[11,12] Small fiber neuropathy (SFN) affects small diameter A delta and C fibers and produces clinical symptoms, and the most sensitive and specific diagnosis is made with intraepidermal nerve fiber density (IEFND).[13] In a study in which SFN was evaluated with T2DM healthy controls, no significant difference was found.[14]

The objective of this study is to compare the electromyography (EMG) test with the SWE method in diabetic polyneuropathy cases that can be observed in T2DM patients. In addition, small fiber neuropathy, which can develop in DM patients, is diagnosed only by clinical findings; the purpose here is to determine the support of sheer wave USG for the diagnosis in these patients.

METHODS

Patients who applied to Kayseri City Hospital Neurology outpatient clinic were evaluated in this study. Approval was obtained from the local ethics committee for the study. The patients were admitted to the study after the necessary explanation was provided about the procedures to be performed, and informed consent form was obtained. In addition, the ethical principles stated in the Declaration of Helsinki were adhered to during the study.

Subjects

Fifty T2DM patients and 16 healthy controls were included in the study. General information such as sex, age, height, and weight of patients and controls were recorded. Body mass index (BMI) was calculated by using weight (kilograms)/height (squaremeter) formula. Persons with another known cause of neuropathy, other peripheral system disease on EMG, other known metabolic and endocrine disease, as well as a known leg, wrist fracture and history of operation were excluded from the study.

Toronto clinical scoring system (TCSS) test, which has been proven to be effective in previous studies[15], was applied to the patients before the NCS, and patients with clinical compatibility with TCSS were included in the study. All patients underwent NCS with a Natus EMG machine by an experienced neurophysiologist (Natus Neurology Inc., Middleton, WI, USA).

The electrophysiological criterion utilized to define polyneuropathy involved the presence of an abnormality in at least one parameter within two or more peripheral nerves across two or more extremities.[16] In this study, NCS was performed, at least one of which was the tibial nerve. Patients were divided into three groups following NCS. The first group was control group with normal NCS. The second group was defined as the SFN group and included 18 patients with normal NCS and diabetes-related complaints (such as burning or penetrating pain and feeling of warmth in the toes, feet) and the third group as sensory axonal neuropathy group included 16 patients with sensory involvement in NCS but without motor involvement. In the fourth group NCS, 16 patients were evaluated as the sensorimotor neuropathy group with sensory and motor involvement. Control group included 16 volunteers without known DM or other disease. Healthy volunteers have not undergone NCS.

Sonographic examinations

The entire study group was examined by a radiologist using SWE and USG. The radiologist was blind to the clinical history and electrophysiological examination results of the patients. Tibial nerve measurements were made at 4 cm proximal to the medial malleolus of both ankles and at the level of both popliteal fossa in the entire study group. Measurements were made in a quiet, temperature-controlled room with the patient lying in the supine position. Toshiba Aplio 500 (Toshiba Medical Systems Corporation, Otawara, Tochigi, Japan) device was used to perform ultrasonography and SWE examinations using a multi-frequency 7 MHz linear transducer. Examinations were performed using grayscale and shear wave elastography.

Statistical analysis

Statistical analyses were made in IBM SPSS for Windows Version 23.0 package software. Numerical variables were summarized as mean±standard or Median [25-75th percentile] values, and categorical variables were summarized as numbers and percentages. Whether the numerical variables showed normal distribution or not was examined with the Shapiro Wilks test. Whether there was a difference between the

two groups in terms of numerical variables was investigated with the t-test in the independent groups in case the parametric test conditions were met, and with the Mann-Whitney U test if it was not. Comparison of more than two groups in terms of numerical variables was done with the Kruskal-Wallis test. Chi-square test was used to determine whether there was a relationship between categorical variables. Significance level was accepted as $p<0.05$.

RESULTS

Fifty T2DM patients (23 female and 27 male), and 16 control group patients (6 male and 10 female) were included in the study. The patients were defined as the control group as Group 1, SFN as Group 2, those with sensory axonal neuropathy as Group 3, and those with sensorimotor neuropathy as Group 4. Age, sex and BMIs of patients are given in Table 1. Patients in Groups 3 and 4 were older compared to the ones in Groups 1 and 2. In addition, there was a statistical difference between Group 1 and Group 3.

In the tibial nerve measurements from the popliteal fossa level of the patients, a significant difference was observed in the area under the curve between the Group 1 and Group 2 on the right side ($p=0.044$). In the measurements of the patients at the medial malleolus level, a significant difference was observed in the shear wave velocity on the right side between group 1 and group 2, and also between group 2 and group 4 ($p=0.047$). When we look at the area under the curve in medial malleolus measurements, statistically significant differences were found between Group 1 and Group 2, and also between Group 1 and Group 3 (Table 2).

There was no significant difference between age and SWE results in correlation of age and BMIs of patients. When evaluated with BMI, however, there were significant differences in correlation especially at the popliteal fossa level (Table 3).

DISCUSSION

A statistically significant difference was found between the SFN and control groups with CSA measurements made at both the popliteal fossa and medial malleolus levels with this study for the first time. It was found that there was a difference in tibial nerve CSA between the patients with diabetic polyneuropathy and small fiber neuropathy and the healthy control group. When the tibial nerve examination at both the popliteal fossa level and the medial malleolus level was evaluated with CSA, a significant difference was found between patients with SFN and healthy controls. Significant CSA differences were also observed between normal patients and patients with sensory axonal neuropathy in measurements at the medial malleolus level. When tibial nerve stiffness was evaluated, it was found to be higher in the DPN groups, however, no statistical significance was observed. Although BMIs differed between the groups, no correlation was found with tibial nerve stiffness.

Electrophysiological examinations are the golden standard in the diagnosis of neuropathy and in providing detailed information about the involved nerves. Nevertheless, it is difficult to tolerate in terms of the difficulty of application and repeating when necessary.[17,18] Recently, USG has started to be used in peripheral nerve diseases because it provides reliable morphological information, is easy to apply, and can clearly visualize the location and range of lesion.[19,20]

In a study comparing only SFN patients with healthy controls, the superficial peroneal nerve was evaluated and no significant differences were

Table 1: Mean age, sex and BMI of patients

	Group 1 (n=16)	Group 2 (n=18)	Group 3 (n=16)	Group 4 (n=16)	p
Age	41.9±9.5*	48.4±11.9#	55.8±10.3*#	64.5±6.7*#	<0.001
Body mass index (kg/m2)	26.0±3.0*	29.8±6.4	31.7±5.4*	31.1±4.4	0.014
Sex (M/F)	6/10 (37.5%/62.5%)	9/9 (50%/50%)	10/6 (62.5%/37.5%)	8/8 (50%/50%)	0.572

Group 1: control group Group 2: patients with SFN Group 3: patients with sensory axonal neuropathy Group 4: patients with sensorimotor neuropathy

* $P < 0.05$ compared with Group1.

# $P < 0.05$ compared with Group2.

Table 2: Comparison of all groups in terms of measurements at popilteal level and medial malleol level of right and left tibial nerve in the areas under stiffness, velocity and curve with Shear Wave Elastography

			Group 1 (n=16)	Group 2 (n=18)	Group 3 (n=16)	Group 4 (n=16)	p
Measurement from popliteal fossa level	SWE (kPa)	Right	25.88±12.68	26.57±17.82	38.54±37.76	31.46±20.94	0.415
		Left	23.82±9.59	20.71±9.86	39.23±38.80	21.03±13.88	0.051
	SWV, m/s	Right	2.82±0.68	2.82±0.86	3.25±1.46	3.04±1.04	0.593
		Left	2.75±0.54	2.55±0.58	3.28±1.62	2.53±0.76	0.104
	CSA, mm2	Right	0.610±0.086*	0.484±0.160*	0.501±0.146	0.510±0.139	0.044
		Left	0.502±0.114	0.487±0.146	0.561±0.188	0.566±0.106	0.273
Measurement from 4 cm above medial malleol	SWE (kPa)	Right	29.99±11.70	33.39±20.94	49.05±44.07	50.94±30.12	0.096
		Left	36.56±14.13	33.32±19.36	44.63±38.16	39.11±19.60	0.592
	SWV, m/s	Right	3.07±0.66*	3.07±0.84#	3.71±1.57	3.96±1.16*#	0.047
		Left	3.38±0.71	3.21±0.79	3.56±1.47	3.49±0.82	0.747
	CSA, mm2	Right	0.272±0.075*	0.180±0.066*	0.218±0.074	0.229±0.051	0.002
		Left	0.265±0.087*	0.178±0.054*#	0.202±0.058*	0.244±0.047#	0.001

CSA cross-sectional area, SWV shear wave velocity, SWE shear-wave elastography
* P < 0.05 compared with Group1.
# P < 0.05 compared with Group2.

found.[14] In a study combining tibial nerve stiffness with TCSS, it has been shown that SWE was effective, suggested that it was a better alternative to CSA, and also predicted that subclinical DPN diagnosis can be made with SWE.[10] In our study, it has been found that the stiffness increased with SWE but did not achieve statistical difference. When it was evaluated with CSA, it has been found that there is a statistically significant difference between the DPN group with normal patients and also between the subclinical DPN group and the control group similar to this study. In another study evaluating the tibial nerve, significant tibial nerve stiffness was observed between patients with DPN and control patients, and although more stiffness was found between diabetic patients without DPN and controls, no statistically significant difference was found.[7] The cause of the more stiffness is DPN group is; stiffness is more pronounced in DPN than in SFN due to DPN's involvement of both large and small nerve fibers. Additionally, DPN's extensive axonal damage to motor fibers and severe microstructural changes, such as microvascular damage, glycation, and fibrosis, contribute to tissue rigidity and stiffness. In contrast, SFN primarily affects small sensory fibers, with minimal motor involvement and fewer microstructural changes, resulting in less stiffness. Similar to our study, in a study in which the tibial nerve was measured at medial malleolus level and compared with CSA, a significant difference was observed between the patients with DPN and the control group, however, no difference was observed between the DM patients without DPN and the control group.[19] In another study conducted with SWE on patients with DPN, although an increase in tibial nerve stiffness was observed, unlike our study, no significant difference was found when it was evaluated with CSA.[21] In some studies, no significant difference was observed between the DPN group and the control group when evaluated with CSA.[22] In our study, a significant statistical difference was found in the measurements of the tibial nerve, especially in the medial malleolus measurements, which were evaluated from 2 different locations. When evaluated with BMI, however, there were significant differences in correlation especially at the popliteal fossa level. This may be due to the fact that the tibial nerve has an optimal threshold at a measurement of 4 cm above the medial malleolus[23] and is less affected by BMI.

Diabetic peripheral neuropathy can cause serious problems which start at an early stage, which may cause a decrease in the quality of life of patients as well as poor outcomes in the future. Therefore, early diagnosis and treatment is important. The change in nerve stiffness can be explained with different mechanisms. Conditions such as sorbitol and fructose accumulation and

Table 3: Correlation of age and BMI with popliteal fossa and medial malleolar measurements

		Popliteal fossa				Medial malleol			
		Right		Left		Right		Left	
		Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p	Correlation coefficient	p
AGE	SWE (kPa)	-0.218	0.078	-0.144	0.250	0.034	0.788	-0.097	0.438
	SWV, m/s	-0.212	0.088	-0.144	0.249	0.052	0.676	-0.086	0.493
	CSA, mm2	-0.085	0.497	0.385	0.001	-0.184	0.140	0.065	0.603
BMI	SWE (kPa)	-0.328	0.016	-0.337	0.013	0.000	0.998	-0.065	0.641
	SWV, m/s	-0.333	0.014	-0.341	0.012	0.016	0.910	-0.05	0.719
	CSA, mm2	-0.051	0.712	0.261	0.056	-0.093	0.504	-0.127	0.360

BMI = body mass index, CSA cross-sectional area, SWV shear wave velocity, SWE shear-wave elastography

increased glycation end products, oxidative stress, microvascular abnormalities, inflammatory processes in patients with DM may cause ischemia and intranerve edema. As a result of this, loss of axons called DPN and nerve degeneration may occur.[17,24] It is generally believed that DPN results from a process in which edema within the nerve bundle increases intraneural pressure and nerve stiffness. It has been observed that increased stiffness causes compression in the microvascularity and deterioration of blood flow, resulting in demyelination and axonal degeneration with a fibrotic response in nerves.[25,26] These pathophysiological changes are considered to be the cause of increased nerve stiffness as indicated with SWE measurements.[8] It has been reported that CSA change in the tibial nerve can be an early sign of neuropathy and can be used as a new instrument.[27] In addition, it was emphasized that USG could be an alternative method in the diagnosis of DPN in addition to electrophysiological methods.[28] Other studies also found CSA and nerve stiffness change.[7,29] A change was found in CSA in our study similar to other studies, and it was shown that the SWE method could be an alternative method to electrophysiological methods for the diagnosis of DPN. In addition, our study has shown that it could be a new useful objective method for SFN that could not be diagnosed by electrophysiological methods, since there was a significant difference in the SFN group compared to healthy controls. Since elastography is an operator-dependent test, it is not currently a standard in the diagnosis of neuropathy. However, it can be considered as an auxiliary test to other standard tests.

TCSS used in our study is an important scoring system, especially in the evaluation of the function of small nerve fibers. Small nerves tend to be damaged in the early stages of patients with DPN, therefore, it is an appropriate test for early screening.[30] In a previous study in which TCSS and tibial nerve stiffness were correlated, a correlation was observed between them. In our study, it was applied in order to demonstrate that small nerves are involved and since it is a more objective test.

There were some limitations in our study; these included only a limited number of patients in the T2 DM group, and type 1 DM patients were not included in the study. Although the tibial nerve was evaluated from two lower extremities and two different regions, other nerves were not evaluated. We could not confirm nerve stiffness as the patients have not also undergone histopathology for the diagnosis of SFN.

In this study, significant differences were found between DPN patients and healthy controls when evaluated with CSA. In conclusion, SWE may be an auxiliary test objective diagnostic method even in cases where DPN cannot be diagnosed with electrophysiological tests. It has been shown for the first time in our study that SFN, which requires biopsy for the definitive diagnosis, can

be diagnosed with USG methods. Multi-center prospective or longitudinal studies with more patient participation are needed to determine cut-off values and use them more effectively.

DISCLOSURE

Ethical approval: Ethics approval was obtained from Local ethical council. Informed consent was obtained from all individual participants included in the study.

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Conflict of interest: None

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